Testimony
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US Influenza Supply and Preparations for the Future

Statement of
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Mr. Chairman and members of the Committee, I am pleased to be here today to update you on the Centers for Disease Control and Prevention's (CDC) efforts to address the influenza vaccine supply status and our planning for the 2005-06 influenza season. We faced unprecedented challenges during this current influenza season. Due to tremendous collaboration among our public health and private sector partners, our collective ability to modify and enhance our response strategy as circumstances changed, and the cooperation of the public, I am pleased to report that we have been successful in our effort to promote and protect the public's health.

Vaccination is the primary strategy for protecting individuals who are at greatest risk of serious complications and death from influenza. In the face of this season's influenza vaccine supply crisis, CDC, state and local public health officials, vaccine manufacturers and distributors initiated extraordinary partnership activities to address this public health challenge. For example, sanofi pasteur (formerly Aventis Pasteur) provided access to vaccine distribution information to aid in the allocation of the available vaccine supply to those people most in need this season. State and local public health officials also worked closely with CDC to ensure equitable distribution of vaccine to those areas with the greatest need. Together we found new and effective ways to address the sudden, late emergence of a substantial influenza vaccine shortage that had never before occurred. And, importantly, this public-private partnership has successfully distributed 95 percent of the 58 million doses of inactivated influenza

vaccine supply that was available. The unused supply – approximately 3.5 million doses of vaccine are still available for distribution - is about the same percentage we have had remaining at this time in prior years. (3.1 million doses of vaccine remain in the stockpile and sanofi pasteur has approximately 300,000 – 400,000 doses available.)

A total of 61 million doses of influenza vaccines were produced for the 2004-2005 influenza season. This includes approximately 58 million doses of inactivated influenza vaccine and three million doses of the live, attenuated influenza vaccine delivered through nasal spray (e.g. FluMist produced by MedImmune). Of the total supply of influenza vaccines, 93 percent of the doses have been distributed through public and private efforts. Over the past six years, between 87-99 percent of the influenza vaccines produced have been distributed. CDC is doing all it can to ensure that the remaining vaccine gets to those most in need, while at the same time providing state and local public health officials with the flexibility to offer vaccination to other groups as local supply allows.

I also want to acknowledge and thank the nation's health protection heroes -- the people not at high-risk who heeded the call to step aside and forgo vaccination so that those at highest-risk could be protected this influenza season. The cooperative and collaborative spirit of Americans helped us meet this serious

challenge. I also commend the public health and medical communities for their incredible efforts helping to manage this difficult situation.

In addition, we are fortunate that the flu season has been relatively moderate so far this year. I want to caution, however, that the flu season continues into March and April. Influenza is unpredictable and the situation could change in coming weeks.

Despite the challenges this year, I would like to note the tremendous progress we have made in recent years to expand the capacity to respond to an influenza crisis. DHHS has begun investing in new technologies, securing more vaccines and medicines, and preparing stronger response plans. We have made significant investments in protecting the nation against influenza, including increases for CDC influenza vaccine funding for both 317 and VFC purchases, from $5.5 million in FY 2001 to $104 million in the FY 2006 budget request, and creation of Strategic Reserves/Stockpiles, from $0 in FY 2001 to an investment of $70 million in the FY 2006 budget request. These investments are further detailed as follows:

- **New Technologies:** In each of the previous three budgets, the Department of Health and Human Services (DHHS) has asked for at least $100 million. We received $150 million for FY 04 and FY 05 in total. We have asked for $120 million for FY 06. This will help foster introduction of

new technologies for producing influenza vaccine, including cell culture, recombinant protein and DNA based vaccines and ensuring a year-round supply of eggs to grow vaccine viruses and respond to supply and surge capacity. Over the next several years, these new technologies and steps to strengthen existing production capacity may help produce influenza vaccine more efficiently and provide more adaptability to unexpected problems or losses in production.

- **Creating the Nation's First Stockpiles of Influenza Medicines:** For the first time ever, we have created stockpiles of both influenza vaccine and antiviral medications. DHHS initially spent $19 million in FY 2004, and is planning to spend another $50 million in FY 2005 ($70 million in the FY 2006 budget request) to develop a strategic reserve of influenza vaccine. In addition, $21 million in carryover funding originally designated for Chiron vaccine stockpiles in FY 2004 will be allocated for use as appropriate in FY 2005 and FY 2006. CDC purchased Tamiflu, for a total of $87.5 million. The total invested for Rimantadine should be $36 million in FY 2005 to treat 4.25 million adults and on Rimantadine syrup to treat 750,000 children. These stockpiles of influenza vaccine and antiviral medications total about $200 million and give the government new ability to respond when there is a shortage of vaccine.

- **Strength and Stability of the Market:** Maintaining an abundant influenza vaccine supply is critically important for protecting the public's health and improving our preparedness for an influenza pandemic. It is essential to add stability and strength to the U.S. influenza vaccine market. DHHS is trying to strengthen the supply by developing financial incentives for manufacturers to increase production and encouraging new manufacturers to enter the domestic market with licensed vaccine. CDC is also considering plans for the use of Investigational New Drug (IND) influenza vaccine to supplement the licensed vaccine when needed.

- **Improving Access by Covering Costs:** The Centers for Medicare & Medicaid Services (CMS) within DHHS have more than doubled the payment rates for the influenza vaccine and its administration since 2000. Estimates from CMS indicate that $18.75 is expected to be paid for administration costs in FY 2005, up from $3.98 in FY 2002. This increase is helping to encourage providers to administer the vaccine by offsetting some of their costs.

In the remainder of my testimony, I will comment on the status of the current influenza season. I also will summarize events that led to the vaccine shortage announced in October 2004, the steps CDC took to address the problem, and what CDC is doing to prepare for the next influenza season.

THE 2004-05 INFLUENZA SEASON

As I mentioned previously, influenza seasons are highly unpredictable. Although epidemics of influenza occur virtually every year, the particular viruses and the beginning, peak, severity, and length of the epidemic can vary widely from year to year. When compared to the 2003-2004 influenza season, the 2004-2005 season has been more moderate so far. However, based on available data influenza in the United States has continued to increase and does not appear to have peaked. As of the week ending January 29, 2005, many states continue to report considerable activity. Sixteen states reported widespread activity. Nineteen states and New York City reported regional influenza activity.

CDC also is monitoring cases of Avian A (H5N1) influenza in Southeast Asia, in collaboration with the World Health Organization (WHO). H5N1 is a potential pandemic threat, and we are communicating each day with our colleagues to assess this situation and what steps should be taken.

CDC RESPONSE TO THE 2004-05 INFLUENZA VACCINE SHORTAGE

On October 5, 2004, Chiron Corporation notified DHHS that none of its influenza vaccine (Fluvirin®) would be available for distribution in the United States for the 2004–05 influenza season. This action prevented the release of its vaccine for this influenza season, reducing by approximately one-half the expected supply of inactivated influenza vaccine available in the United States for the 2004–05 influenza season. In response to the loss of Chiron vaccine, both sanofi

pasteur and MedImmune increased production of influenza vaccine to provide additional doses for the season, with sanofi pasteur producing approximately 58 million doses of inactivated vaccine and MedImmune producing approximately three million doses of the intranasal, live attenuated vaccine. HHS and CDC acted quickly in response.

Interim Influenza Vaccination Recommendations for the 2004-05 Season

On October 5, the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for influenza vaccination during the 2004-05 season. The interim recommendations identified the priority groups of people that should receive the limited supply, including people who are most vulnerable to develop serious complications and even death from influenza: adults 65 years of age and older, children 6 to 23 months of age, individuals with certain chronic underlying medical conditions, pregnant women, residents of nursing homes and long-term care facilities, and children on chronic aspirin therapy. In addition, the ACIP recommended vaccination for individuals who might otherwise spread influenza to high-risk individuals, including household contacts of infants less than six months of age and healthcare workers providing direct, hands-on patient care. These interim recommendations took precedence over earlier recommendations.

In December 2004, the ACIP broadened the interim influenza vaccination recommendations to include older adults 50-64 years of age and household contacts of all high-risk persons six months of age where state and local public

health officials judged the supplies of vaccine to be adequate. The revised recommendations went into effect January 3, 2005. In addition, ACIP expanded the use of vaccine for children Vaccines for Children (VFC)–purchased influenza vaccine to include VFC eligible household contacts of high-risk VFC children six months of age and older.

On January 27, 2005, CDC issued a Health Alert Network announcement encouraging the continued targeting of vaccine to the priority groups while also encouraging state and local public health officials to make the best use of the remaining vaccine by broadening vaccination recommendations further, as warranted by local supply and public demand.

Influenza Vaccine Supply and Allocation Plan

Following the Chiron withdrawal, sanofi pasteur – which had already distributed 33 million doses by October 5, 2004 - announced that it would work with CDC to develop a plan to target the remaining 25 million doses of influenza vaccine toward providers serving the populations at greatest risk for serious complications from influenza. In addition, state and local health officials have worked together with CDC, sanofi pasteur, and a number of vaccine distributors to assure the most equitable and efficient means of distributing the remaining, limited supply of vaccine across the nation. The significant contributions and leadership of these public health professionals has contributed to our nation's effective response to this public health challenge.

Every effort has been made to distribute vaccine to as many providers serving high-risk populations as possible in a timely fashion. The vaccine distribution process this season reflected constant feedback to CDC, and changes were made based on evolving information about vaccine supply, need and demand. Initially, CDC worked closely with sanofi pasteur to fill the public and private orders of health care providers and facilities serving high-priority persons, including orders placed with both sanofi pasteur and Chiron. During the months of October and November, approximately 13 million doses of vaccine were distributed to:

- State and local health departments;
- The Vaccines for Children Program;
- Pediatric providers and other primary care providers;
- Healthcare providers who had ordered sanofi pasteur's preservative-free influenza vaccine (licensed for use with children 6-35 months of age);
- The Department of Veterans Affairs;
- The Indian Health Service;
- Long-term care facilities and acute care hospitals;
- The Visiting Nurses Association of American; and
- The Department of Defense.

In early November three to four million doses were used to fill the remaining public health orders. In addition, state health officials and CDC worked together,

in consultation with local health departments, to develop a formula for the equitable distribution of the eight million remaining influenza vaccine doses to be shipped. This formula took into account the population of high-priority individuals in each state and the number of influenza vaccine doses that had already been shipped to each state. Based on state reports regarding the adequacy of their vaccine supply to meet the needs of the priority populations in their jurisdiction, CDC made three re-apportionments of vaccine across the states to assist those states that continued to have unmet need for vaccine.

To further ensure the equitable apportionment of vaccine, CDC implemented a secure web-based application, the Flu Vaccine Finder, and made it available to state health officials to identify doses of inactivated influenza vaccine shipped to their state during the 2004-05 influenza season in relation to the location of priority populations within their jurisdiction. This secure web-based application also served as the mechanism through which states placed their vaccine orders.

Some states purchased vaccine to distribute and administer. However, the majority of vaccine was allocated for purchase by private sector providers and facilities. During the months of November and December 2004 and January 2005, states allocated approximately 4.6 million doses to health care providers.

Finally, to enhance continued use of late season influenza vaccines, CDC developed two strategies to make vaccine available to public and private providers with minimal financial risk.

- CDC made available to sanofi pasteur the remaining 3.1 million doses of influenza vaccine in the federal government's emergency reserve. Sanofi pasteur, in turn, is marketing the vaccine to public and private providers. This strategy will allow providers to order vaccine directly from sanofi pasteur or a vaccine distributor, instead of working through state or local health departments. Doses purchased in this way may be used in any person in accordance with the Advisory Committee on Immunization Practices (ACIP), state, and local recommendations for vaccine use.

- CDC is taking steps for the remainder of this influenza season to make limited amounts of VFC influenza vaccine that currently exists within states available to state health departments for non-VFC use where the demand for influenza vaccine among VFC-eligible children has already been met.

Additional Sources of Influenza Vaccine

Approximately three million doses of MedImmune's intranasal, live, attenuated influenza vaccine, FluMist, were produced for the 2004-05 season. This vaccine

was recommended for use among healthy persons ages 5–49 years who are not pregnant, including healthcare workers (except those who work with severely immunocompromised patients in special care units) and household contacts of infants less than 6 months of age. CDC continues to make people aware of this alternative to inactivated influenza vaccine.

DHHS successfully located and purchased approximately 1.5 million doses of influenza vaccines licensed for use in many countries around the world. Because these vaccines are not currently licensed in this country, they must be administered under special protocols with written consent. Preparations for the use of these vaccines have been completed through the Food and Drug Administration's approval of Investigational New Drug (IND) protocols and implementation of a contract with a contract research organization that is prepared to administer the IND vaccine and complete the required follow-up activities in areas with unmet demand and inadequate supply of licensed vaccine during this season.

Monitoring Influenza Coverage

To assess influenza vaccine coverage among the priority populations and to learn more about the reasons members of the priority populations chose to go unvaccinated, CDC included additional influenza questions on the Behavioral Risk Factor Surveillance System (BRFSS) survey. BRFSS is a telephone survey

conducted by state health departments that provides state level and national estimates regarding health behaviors, such as immunization behaviors.

Data collected January 1 through 22nd, 2005 suggest that influenza vaccination uptake continued through the month of December. Vaccination coverage among adults in all priority groups was 43 percent this year, while coverage among non-priority adults was eight percent, suggesting that targeting of influenza vaccine has been effective. Among adults aged 65 years of age and older, nearly 59 percent reported influenza vaccination this season. Vaccination coverage among children in priority groups was 51 percent.

Antiviral Medications

Although vaccination is the primary strategy for protecting individuals who are at greatest risk of serious complications and death from influenza, influenza antiviral medications are an important adjunct to influenza vaccine in the prevention and treatment of influenza. CDC has developed interim recommendations on the use of antiviral medications for the 2004-05 influenza season. The interim recommendations were developed to reduce the impact of influenza on persons at high risk for developing severe complications secondary to infection. The recommendations are not intended to guide the use of these medications in other situations, such as outbreaks of avian influenza in humans.

Influenza antiviral medications have long been used to limit the spread and impact of institutional influenza outbreaks. They are also used for treatment and chemoprophylaxis (prevention) of influenza in other settings. In the United States, four antiviral medications -- amantadine, rimantadine, oseltamivir, and zanamivir -- are approved for treatment of influenza. When used for treatment within the first two days of illness, all four medications are similarly effective in reducing the duration of illness caused by Strain A influenzas by one or two days. Only three antiviral medications (amantadine, rimantadine, and oseltamivir) are approved for prevention of influenza.

If supplies allow, CDC encourages the use of amantadine or rimantadine for prevention of influenza, and use of oseltamivir or zanamivir for treatment of influenza. People who are at high risk of serious complications from influenza may benefit most from antiviral medications.

The United States has a supply of influenza antiviral medications for both adults and children stored in the Strategic National Stockpile for emergency situations. Procurement of additional supplies of antiviral medications, and shipments arrive weekly. Antivirals will be made available to states and territories for use in outbreak settings, as might occur in a hospital or long-term care facility, if supplies from commercial sources become depleted or are not available quickly enough to be of use. Our stockpile includes antivirals effective against Avian A

(H5N1) influenza, which we will work to maintain in reserve to be used in the event of an influenza pandemic.

Communicating the Public Health Message

The October 5 Chiron announcement led CDC to rapidly revise its influenza message strategy, and target considerably narrower population subsets than had been originally planned. Key messages provided a rationale for reserving limited influenza vaccine for the most vulnerable populations, while appealing to all others to defer vaccination in the interest of reserving the limited vaccine stocks for those at greatest need.

In refocusing its campaign, CDC set specific objectives:

- To encourage specific groups at greatest risk of influenza complications to receive the vaccine;
- To gain voluntary approval of all others to step aside;
- To encourage late season vaccination beyond the typical high-demand months of October and November, by reminding both the public and health care providers that influenza vaccination is effective throughout the winter influenza season; and
- To introduce the concept of offering imported vaccine, under special arrangement, as an alternative source to help meet demand and public health need for additional vaccine.

CDC outreach included:

Communication with state/local public health partner audiences via the electronic Health Alert Network (HAN).

Between October and January, six HAN dispatches were shared with the public health community detailing the interim recommendations for influenza vaccine, antiviral medication, the reallocation of vaccine stocks, and guidance for late-season influenza vaccination.

Continuous information updates through The National Public Health Information Coalition (NPHIC).

The NPHIC is a group of professional public health communicators from all 50 states and large city public health agencies. Through frequent conference calls, this group became aware of upcoming communications materials, and identified specific communications needs for their areas. The messages developed through these interactions included advice for minimizing the risk of influenza and encouraging late-season vaccination, in areas where sufficient stocks remained.

Hotline, website and media relations outreach

Through its information hotline, website, and news media relations, CDC communicated openly with the public from the start of the influenza vaccine

shortage. For example, from October 1, 2004 through January 31, 2005 the hotline fielded more than 60,000 calls. The CDC flu website recorded 12 million page views during this same period. CDC has also handled almost 1400 media calls related to vaccine availability and participated in satellite media tours to provide the latest information to broadcast media representatives.

CDC sustained a focused effort to maintain regular communications with doctors, clinicians, and other health care providers through a variety of channels, including providing detailed updates to 40,000 health care providers who subscribe to CDC's clinician registry e-mail list-serve and through conference calls. CDC also established a special Clinician Information Line, which was available 24 hours a day, 7 days a week. More than 2,600 calls, answered by professional registered nurses, have been answered through the end of January.

In addition to these efforts, CDC has issued news releases concerning influenza vaccine availability, conducted formal news briefings, and worked to incorporate both radio and television recorded new releases into its outreach efforts.

CDC also made specific efforts to reach business and educational institutions with critical information about the priority populations recommended for vaccination and alternative methods for preventing transmission of disease in the workplace and educational settings.

PREPARATIONS FOR THE 2005-06 INFUENZA SEASON

Anticipating and planning for the next influenza season is an enormous and highly-complex challenge, involving numerous public health and private sector entities. The production of influenza vaccine is a lengthy and complicated process. There are currently two manufacturers licensed to produce influenza vaccines for the United States. Currently one manufacturer produces inactivated influenza vaccine and one manufacturer produces the live, attenuated vaccine administered through nasal spray. Manufacturers must predict demand and decide how much of the vaccine to produce six to nine months before the influenza season begins. Moreover, the severity of influenza season and potential public demand for vaccine are highly unpredictable from year to year.

Currently experts from the four World Health Organization (WHO) Collaborating Centers in the United States (Atlanta), Australia, Japan and the United Kingdom, along with regulatory authorities including the FDA, are in Geneva at WHO making decisions about which vaccine strains to include in next year's Northern hemisphere vaccine. They are analyzing global data including important surveillance information gathered by CDC. On February 17-18, experts in the U.S. will meet in Washington at the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to make decisions about the influenza vaccine for the upcoming season in the U.S.

CDC has already begun its planning efforts for the 2005-06 influenza season in anticipation of continued challenges in meeting the nation's vaccine supply needs. To date, CDC has:

- Developed possible scenarios for vaccine supply for the coming season, including the possible exit of current influenza vaccine manufacturers from the U.S. market; the entry of new vaccine manufacturers into the U.S. market; and the possible need for use of IND influenza vaccine to meet demand.
- Worked with ACIP to develop more refined prioritization plans that can be used should there be another critical vaccine shortage.

In addition, CDC is:

- Meeting with U.S.-licensed and other vaccine manufacturers to discuss their plans for the next season, including production, distribution, and pre-booking plans.
- Planning a vaccine contracting strategy that addresses routine influenza vaccine purchase and stockpile purchase.
- Preparing for the possible use of IND influenza vaccine as part of the 2005-06 influenza vaccination program.
- Monitoring antigen-sparing studies which are designed to determine if reduced vaccine dosages can provide sufficient immunity against influenza and thus allowing for the protection of more persons with fewer doses of vaccine will help control the spread of influenza.

- Developing infection control strategies.
- Developing and implementing an evaluation plan.
- Preparing communication strategies with appropriate messages to respond to the fluctuations in supply and demand anticipated throughout the season.

These comprehensive planning efforts are intended to help us achieve important public health objectives to increase domestic production of influenza vaccine, increase demand for vaccine in order to protect and improve public health, and increase vaccination coverage, particularly among high-risk groups.

CONCLUSION

CDC's agency-wide influenza budget request for FY 2006 totals $197 million, nine times more funding than in FY 2001. In addition, DHHS has increased its investment in influenza-related activities from $42 million in FY 2001 to $439 million in FY 2006.

Our nation's response to the circumstances presented in October 2004, as well as the efforts now underway to prepare for the next season and beyond, indicate the seriousness of influenza as a public health threat. We addressed the urgent situation as effectively and expeditiously as possible to provide vaccine to those most in need of health protection. Our targeting efforts were highly successful,

and in our future-year planning, we already are applying lessons learned from the challenging experiences of the 2004-05 influenza season.

Thank you for focusing attention on this important public health issue and for the opportunity to provide an update on our current efforts. CDC is committed to protecting and promoting health for all Americans, preventing disease and disability through public health research and public outreach, and supporting important public health interventions, including vaccination. We appreciate your interest in this issue and your support of CDC's efforts to protect the public's health.

I will be happy to answer any questions.